



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,434	02/28/2001	Wilfried Fischer	2727-130	5919

7590

07/25/2002

RONALD R. SANTUCCI
745 FIFTH AVENUE
NEW YORK, NY 10151

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/25/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,434

Applicant(s)

FISCHER, WILFRIED

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,10-15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,10-15 and 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 6) ☐ Other: _____

DETAILED ACTION

Amendment B, the IDS, and Change of Address filed on March 21, 2002 are acknowledged. Amendment C filed on May 8, 2002 is acknowledged.

Claims 1, 3-5, 8, 10-15, and 17-32 are included in the prosecution of this application.

Claims 2, 6-7, 9, and 16 are cancelled.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 8, 10-15, and 17-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in combination with WO 89/07959.

WO 95/24172 discloses transdermal delivery system, which has a backing (cover layer), a pressure-sensitive adhesive drug composite layer, and a release liner (protective layer) (Note Fig. 1). The reference teaches a gelled drug layer containing hydroxypropylcellulose between two active-free adhesive layers (pg. 19, line 1 and Fig. 1). The art reads in instantly claimed thickness (pg. 16, lines 20-23). The backing and release liner are made of silicon polyester (pg. 15, line 5 and Ex. 2). Other materials that may be used for the backing layer are polyterephthalic acid ester, polyurethane,

Art Unit: 1616

polyethylene, or polypropylene (pg. 15). WO teaches the use of the device for treating nicotine withdrawal (pg. 2, lines 5-23) and nicotine can be mixed with HPC or other gelling agents such as petroleum jelly, etc (pg. 19). WO 95/24172 teaches a transdermal delivery system and discloses materials that may be used in the adhesive layer such as polyurethane (pg. 16, lines 23-37 and claim 9).

WO does not teach the active agent in a hydrophobic solvent or perforations in the drug layer.

WO 89/07959 teaches an occlusive body patch for transdermal administration of active agents. WO teaches nicotine in tee tree oil which is then mixed in a water-soluble polymer (methyl cellulose) (example 1). The reference teaches the use of a microporous polymer in the active layer such as polypropylene or polyethylene (Note Abstract, pg. 15, lines 22-25, and pg. 7, lines 11-25). The perforations in the active layer allow it to come in contact to the cover layer and adhesive layer. Further, the reference discloses that nitroglycerine may be substituted for nicotine and teaches the use of testosterone (pg. 11, line 11 and claim 11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of both references since both teach transdermal patches. One would be motivated to have a microporous polymer in the active layer to control the rate of release of the drug. Further, one would be motivated vary the drug used in the transdermal system since the active agent is dependent on the type of disorder treated, thus for example one would use nitroglycerine, a transdermally administered agent, to treat Angina pectoris or nicotine for nicotine

withdrawal in a the transdermal drug delivery system such as WO 95/24172. One would be motivated to include a mixture of more than one drug in the transdermal system in order to treat different disorders simultaneously.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in combination with WO 89/07959 in view of Wick et al (5679373).

As set forth above, WO 95/24172 and WO 89/07959 teach transdermal systems. WO 95/24172 exemplified methylcellulose as the water-soluble polymer in the drug layer.

The references do not teach the use of gelatin as the water-soluble polymer.

Wick et al teach a transdermal patch that has a backing layer, a release layer, an adhesive layer, and a drug layer (Note Figure). Wick teaches the active agent permeable adhesive layer to be dermatologically acceptable such as methylcellulose or gelatin, among others which permits drug migration (col.16, line 59 to col. 17, line19).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute gelatin for the water-soluble since Wick et al teach methylcellulose and gelatin to be dermatologically acceptable to the skin of the host. Therefore, one would be motivated to use gelatin in the WO references with the expectation of similar results.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in combination with WO 89/07959 in view of Place et al (5242391).

As set forth above, WO 95/24172 and WO 89/07959 teach transdermal systems.

The references do not teach the combination of instant drugs.

Place et al teach the treatment of erectile dysfunction. On column 3, a line 12-20, Wick discloses the use of testosterone for the treatment of impotence in the prior art. Place teaches the topical application of nitroglycerin to treat impotence (col. 4, lines 30-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a mixture of nitroglycerin and testosterone in a transdermal system to treat impotence. One would be motivated to do so with the expectation of an additive effect in treating impotence.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

July 17, 2002


MICHAEL G. HARTLEY
PRIMARY EXAMINER